

# **Impact of Visual Impairment Assessment on Functional Performance in Stroke Patients: A Pilot Randomised Controlled Trial**

## **Abstract:**

**Aim:** To determine whether providing therapy staff with objective information regarding the nature of visual impairment enhances functional recovery.

**Methods:** A mixed methodology incorporated a pilot randomised controlled trial (RCT) and qualitative study. Patients presenting acutely with functional disability and suspected visual deficit, underwent visual assessment. Patients with visual impairment were recruited; all subjects received rehabilitation. The sample was randomised to group A (control) where details of visual assessment were withheld from therapy staff and group B (experimental) where details of visual assessment were disclosed. Functional measures (Functional Independent Measure, timed walk) were recorded at baseline and 6-week follow-up. Health professionals participated in a focus group to discuss the perceived influence of the additional visual assessment service on functional outcome.

**Findings:** 64 patients were recruited over 18-months (group A=31; group B= 33).

Drop out resulted in 19 subjects in group A and 20 in group B for full analysis.

Significant functional improvement was noted in both groups, no significant difference was found between groups. Health professionals reported a perceived positive impact from the vision assessment service.

**Conclusions:** Provision of visual assessment information did not influence functional recovery. Qualitative findings indicated perceived benefits from the provision of the vision assessment service.

**Keywords:**

Stroke, functional outcome, vision assessment, mixed methodology, multi-disciplinary approach

**Introduction**

Visual impairment has been reported in up to two thirds of stroke survivors (Clisby, 1995; Rowe, 2009; Jones and Shinton, 2006) and thus is a common occurrence following stroke. There are many types of visual impairments which have been largely categorised as eye movement abnormalities, visual field loss, poor central vision and visual processing and attentional deficits (Clisby, 1995; Rowe, 2009; Jones and Shinton, 2006; MacIntosh, 2003; Freeman and Rudge, 1988).

An association is recognised between the presence of visual impairment and impaired activities of daily living and vision-related quality of life (Gall et al, 2009; Jongbloed, 1986; Dombovy et al, 1986). Specifically, visual impairment can cause difficulty with recognition of objects and faces, visual memory, executive functioning and searching and locating information which in turn provides challenges in interpreting visual information (Wolter and Preda, 2006; Warren 2009). Visual impairments have been shown to frequently impact on everyday activities such as functional mobilisation (Lamoureux et al, 2009, Warren, 2009) and reading (Rowe et al, 2011b; Lamoureux et al, 2009). There is evidence that stroke survivors with visual field loss find valued occupations such as shopping, financial management, viewing television, driving and meal preparation difficult (Warren, 2009). Visual impairment is

likely to result in reduced participation in a wide variety of activities of daily living including hobbies and social interaction (Jones and Shinton, 2006; Lamoureux et al, 2009; Warren, 2009). There can also be an impact on ability to participate in rehabilitation programmes and to return to independent living, as well as an increased likelihood of developing depression and an increased risk of falls (Jones and Shinton, 2006; Ramrattan et al, 2001).

Although the literature clearly documents that the presence of visual impairment impacts on activities of daily living and quality of life, there is little evidence indicating how the presence of visual impairment affects the choice of rehabilitation undertaken by the therapy team or how visual impairment may affect the recovery of functional performance. Recent surveys have shown the lack of formal visual assessment for stroke patients with visual problems and inconsistency within stroke units with regard to policies on visual assessment and referral for treatment (Rowe, 2010, Pollock, 2009). This is despite national recommendations that all stroke survivors with visual impairment should be referred for specialist visual assessment (Department of Health, 2007; Royal College of Physicians, 2008; Scottish Intercollegiate Guidelines Network, 2010). Screening by members of a stroke team has been shown to lack accuracy in comparison to detection of vision impairment by specialists in eye care (Rowe et al 2011a), although provision of accurate visual screening information has been reported as being perceived as beneficial to patients and therapists (Brand, 2009).

We sought to undertake a pilot study comprising a small randomised controlled trial (RCT) with a target population of patients with confirmed visual impairment to determine how provision of detailed visual assessment might impact on delivery of overall functional rehabilitation and outcome. Our hypothesis was that providing

therapy staff with objective information regarding the nature of visual impairment post stroke would enhance functional recovery.

## **Methods**

A pilot RCT was undertaken to establish the impact of objective information from a vision assessment on the functional recovery during in-patient rehabilitation. A pilot RCT was selected as there has been very little previous research in this area, therefore there was a need to test the outcome measures and sample size, and to establish potential biases for future studies. This was supplemented by a focus group which explored health professionals' views of the additional vision assessment service that was provided by an eye care specialist (Orthoptist) as part of the pilot RCT. The studies were undertaken with National Research Ethics Service approval (reference number:07/H0402/39), local research and development unit approval and conformed to the Tenets of the Helsinki Declaration.

### **Quantitative Study**

Participants were prospectively recruited between February 2008 and July 2009 from the stroke unit at Warrington and Halton Hospitals NHS Foundation Trust. It was not possible to accurately calculate a power sample size as the effect of visual input on therapeutic outcome was unknown at the time of planning this trial. A prospective observation cohort study in the UK suggested that of all stroke patients referred with suspected visual impairment, 85% were found to have an identifiable visual impairment (Rowe, 2007). On the basis of this preliminary data, this pilot study aimed to screen 100 patients in order to recruit a minimum of 70 participants.

All patients admitted to the unit between these dates were considered for inclusion in the study. Participants were eligible for inclusion if they had a stroke within 2-6 weeks of being recruited, had a decreased functional ability compared to pre-stroke functioning, had a post-stroke visual impairment and were able to understand the research process. They were excluded if they were unable to consent due to cognitive impairment or communication difficulties, or if they had a visual field impairment pre-existing their stroke. Specified members of the health care team (nurses, stroke physicians, physiotherapists and occupational therapists) on the stroke unit were required to screen patients against these criteria to identify potential participants. Staff used a screening form with questions to identify visual signs (head turning, strabismus, ptosis) and symptoms (diplopia, loss of vision, field loss). This was adapted from the screening form used in the Visual In Stroke (VIS) study (Rowe, 2010). If visual impairment was noted, the screening form was sent to the Orthoptist and hence, it doubled as a referral form.

Those with a suspected visual deficit were informed of the trial and provided with a written information sheet. All patients happy to proceed gave signed consent. Where necessary, for example when a potential participant had communication difficulties, adaptations were made to the consent process in line with the study ethical approval. Witnessed consent was obtained in circumstances where a patient was able to understand the patient information and could gesture their consent, but were unable to sign the consent form themselves. All patients giving valid consent were seen by an orthoptist for a full visual assessment. Patients who had a visual impairment confirmed by the Orthoptist were entered into the trial. Patients who did not present with a visual impairment were excluded at this stage. All patients with visual

impairment requiring any additional visual assessments or treatment were referred to the eye clinic to ensure follow-up separate to the trial.

### ***Intervention***

The participants were recruited by a member of the research team based at the hospital. They were then randomised into one of two groups by use of a computer generated randomisation table. The randomisation process was administered by a researcher at the University of Liverpool, who was not involved in data collection but was involved in the later data analysis. Participants were masked to group allocation, but the assessors were not masked in this trial.

As previously stated, all participants underwent a full visual assessment by an Orthoptist. The findings from the visual assessment were withheld from the therapy staff in group A (control group). In comparison the visual assessment details were made available to the therapy staff for participants in group B (experimental group). Although participants in both groups received occupational therapy and physiotherapy, the difference in intervention between the groups was that the treatment of those in group B was informed by the results of the visual assessment, whereas the treatment of those in group A was not. Therapy routinely included working to regain motor activity and increase ability to achieve valued functional tasks. The therapists used strategies such as visual scanning and cueing to the affected side as part of their practice. The study hypothesis is based on a belief that having access to visual assessment information would make therapy more effective through more accurate application of strategies in therapy to overcome visual impairment.

The pilot study was planned assuming approximately 6 weeks of in-patient therapy following recruitment based on average lengths of stay on the stroke rehabilitation unit at the time of planning this trial.

### ***Assessment and Evaluation***

Following recruitment, basic demographic data was collected from case notes including, lesion laterality, type of stroke, distribution of stroke (i.e. cortical, subcortical, mixed) and handedness.

The full baseline visual assessment, completed by the Orthoptist, was a battery of routine tests used as part of a previous study (Rowe et al, 2009). It comprised tests of visual acuity-logMAR (Bailey and Lovie, 1976), ocular alignment -cover test (Pediatric Eye Disease Investigator Group, 2009), ocular motility-saccadic, smooth pursuit and vergence assessment (Holmes et al, 2001), stereopsis-Frisby test (Rosner and Clift 1984), visual field-confrontation (Cassidy et al, 2001) and visual inattention-line bisection, star cancellation and clock drawing (Ferber and Karnath, 2001). This assessment was consistently performed by the same specialist Orthoptist (AMC:author) to ensure standardisation of assessment methods across all participants. The Orthoptist did not suggest possible adaptive strategies to be undertaken, the focus was on alterations made by the therapists based only on the visual assessment information.

The primary outcome measure was a functional assessment comprising the Functional Independence Measure (Granger et al, 1986). A secondary outcome measure consisted of a timed 10 meter walk. The FIM and timed walk were selected to gain a broad overview of function in a busy stroke unit. These measures have been recommended in the literature to measure disability and mobility respectively

(Turner-Stokes, 2005) and are recognised and widely used for this purpose (Wade, 1992, p.84; Turner-Stokes, 2005). These were completed at baseline and repeated at 6 weeks after baseline (or on discharge if this occurred earlier).

The Functional Independence Measure (FIM) is an 18-item, 7-level ordinal scale, used as a measure of disability within medical rehabilitation. Use of the FIM post stroke is well established (Hinkle, 2001) and the measure has proven validity (Granger et al, 1993; Oczkowski and Barreca, 1993) and reliability (Hamilton et al, 1991) within this population.

Measuring gait speed over 10 meters indoors (timed 10 meter walk) has been shown to be a useful, valid and reliable indicator of functional mobility (Hart et al, 2005; Collen, 1990).

In addition to the FIM and timed walk, the therapist with the most contact with each participant was asked to complete a non-validated questionnaire giving qualitative information about their treatment approach. The aim of this therapy questionnaire was to gain an understanding of the clinical reasoning underpinning therapy intervention. Due to the nature of the data being collected, there were two versions of this questionnaire. The group A questionnaire asked the therapist to justify their treatment approach. The group B questionnaire required the therapist to comment on whether their treatment approach had been influenced by the visual assessment.

A direct comparison of each group was made using the statistical package SPSS version 15. Each group was evaluated by the cross tabulation facility (Pearson chi squared  $\chi^2$  test) to determine homogeneity considering factors of gender, stroke laterality, handedness, age, type of stroke, area of stroke lesion. When comparing Groups A versus B at baseline and follow-up (between group analysis) non-



parametric analysis was undertaken with Mann-Whitney test. Data from Group A and Group B (within group analysis) were compared from baseline to follow-up using the Wilcoxon signed-rank test.

### **Qualitative study**

This study incorporated a new vision assessment service. A focus group has the potential to establish how a group of people feel and think about a particular issue (Sim, 1998, p.346) and allows the collection of a large quantity of rich data in a relatively short space of time (Kamberelis and Dimitriadis, 2005, p.903). The aim of the focus group was to establish health professionals' views about this additional vision assessment service and their perceived impact of this service on functional outcome for patients. The study was designed to collect data to supplement the quantitative study.

The most senior member of each profession involved in the quantitative study (nurses, doctors, occupational therapists, physiotherapists, orthoptists) were contacted by e-mail. This e-mail was an invite to all staff involved in the study to participate in a focus group. Staff interested in participating were provided with an information sheet to explain the study, written consent was gained from all staff who were prepared to participate. A second stage consent was completed after the focus group to allow each participant, the opportunity to withdraw or control of the data collected.

The focus group was structured using a Strength, Weakness, Opportunity and Threat (SWOT) framework, to structure perceptions about the vision assessment service. This framework was used to lead a focus group in a semi-structured format. The facilitator structured the focus group by establishing the Strengths, Weaknesses,

Opportunities and Threats of having a full baseline vision assessment service on the stroke unit. This framework provided opportunity for participants to comment on the vision assessment service without the facilitator asking direct questions and leading the discussion.

The facilitator used a social constructionist theoretical approach (Ivanoff and Hultberg, 2006, p.131, Finlay and Ballinger, 2006, p.263) to underpin and guide the focus group; participants were encouraged to express their views and consider their own views in the light of other opinions expressed. The focus group was audio-recorded and transcribed verbatim.

The data were analysed using an inductive methodological approach (Silverman, 2000) compatible with a social constructionist perspective. In NVivo8 the casebook facility was used to record the individual contributions to the focus group. This allowed an analysis of content and amount of speech of each participant and facilitator, and consideration of themes emerging for an individual participant. It also provided the opportunity to analyse whether a participant had changed the views they voiced during the focus group. Preliminary nodes were developed. As the nodes matured, tree nodes were utilised to show the links between the emerging themes. In line with a social constructionist approach (Duggleby, 2005, pp.837-8, Webb and Kevern, 2001, pp.802-4, Ivanoff and Hultberg, 2006, p.129), once this process was complete, the transcript was then analysed again to consider whether the group interaction supported these themes.

This approach accepts that findings are dependent on the context in which they were collected and that the findings are presented with an understanding that this is the researcher's perspective of the data (Finlay, 2006, pp.16-7). The researcher who

analysed the data endeavoured to be reflexive throughout the process using a field log book to facilitate reflections, with the aim of better understanding the group processes and the data.

## **Findings**

### **Quantitative Study**

A total number of 74 patients were identified as meeting the requirements for this trial. Ten patients were excluded from recruitment because of an inability to provide informed, written consent – mainly due to cognitive impairment. Sixty-four patients were recruited to the trial after obtaining informed, written consent.

Group A consisted of the control group and comprised 31 patients (19 male and 12 female) with a mean age of 69.35 years (SD 14.45). Group B consisted of the experimental group and comprised 33 patients (21 male and 12 female) with a mean age of 70.38 (SD 10.77). Comparison of both groups for factors such as type, area and laterality of stroke are shown in table 1. There was no significant difference in the composition of both groups ( $\chi^2$  test) for gender ( $p=0.846$ ), age ( $p=0.113$ ), stroke type ( $p=0.564$ ), stroke area ( $p=0.499$ ), stroke laterality ( $p=0.396$ ) and handedness ( $p=0.268$ ).

*Insert table 1 about here*

Figure 1 depicts the drop out aspects for each group. Initial drop out from the study, due to death or lack of FIM baseline measurement, led to 27 patients in group A and 24 patients in group B with full baseline assessment. Later drop out prior to the 6-week follow-up assessment related to early discharges, death or failure to attend follow-up assessment, leading to 19 patients in group A and 20 patients in group B

with full follow-up assessment. Further analysis of these groups again showed no significant difference in their composition for factors of type ( $p=0.35$ ), area ( $p=0.627$ ) and laterality of stroke ( $p=0.38$ ) plus age ( $p=0.356$ ) and ocular diagnosis ( $p=0.687$ :  $\chi^2$  test).

*Insert figure 1 about here*

All data analysis was conducted based on the recruited patients to each group with full FIM data collection for both baseline and 6-week follow-up assessment.

Comparison of both groups for factors such as type, area and laterality of stroke are shown in table 2

*Insert table 2 about here*

The median FIM scores are shown in table 3. There was no significant difference in this primary outcome measure between groups at baseline assessment ( $p=0.94$  Mann Whitney test). A significant improvement in FIM score was seen over the 6-week follow-up period from a median of 73 to 104 in group A ( $p=0.0001$ , Wilcoxon test) and 75 to 95 in group B ( $p=0.001$ , Wilcoxon test). Although there was a slightly greater improvement in FIM median score for the control group, this was not significant ( $p=0.29$ , Mann Whitney test). For the secondary outcome measure of a timed walk score, it was not possible to consistently capture this data for all participants at the follow-up assessment because of clinical constraints. The timed walk score was available for 0 participants in group A and 3 in group B at baseline and 5 participants in group A and 5 in group B at 6-week follow-up. It was not possible to draw any conclusions from this secondary outcome measure due to the limited amount of data, therefore the timed walk results have not been presented.

*Insert table 3 about here*

Limited information was provided on the questionnaires. In group B (experimental group), the therapy questionnaire revealed one case in which the therapist stated they had made a change to their choice of treatment, however the change of treatment was not specified by the therapist. This patient had an ocular diagnosis of visual field loss combined with eye movement deficits with a baseline FIM score of 70. The patient was unable to complete the timed walk. In three other cases the therapists stated that the assessment information did not alter their choice of treatment, but that their approach to the patient during treatment was altered. Again, there was insufficient detail given on the questionnaire to indicate how their approach had altered. Of these three cases, one patient had visual perceptual difficulties with a FIM score of 98 and was unable to complete the timed walk, the second patient had visual field loss combined with eye movement deficits with a FIM of 99 and timed walk of 13 seconds. The third patient had visual field loss combined with visual inattention and a FIM score of 87 and was unable to complete the timed walk. In these cases the patients did not exhibit any specific differences in comparison to the measurements taken for other patients in their group. There was no indication as to what informed these decisions.

### **Qualitative Study**

Four health professionals participated in the focus group. Physiotherapy (PT), occupational therapy (OT), orthoptics (Orth) and the medical staff (Dr) were represented. Nursing had indicated that they would be represented, but on the day of the focus group a nurse was not able to attend.

Three main themes were identified during thematic analysis of the focus group.

### *Importance of Vision Assessment Service to Health Professionals*

All participants in the focus group indicated that they thought a full baseline visual assessment service was important. This vision service was viewed as promoting knowledge of visual problems and raising their priority. One participant (Dr) stated *'we too frequently forget about visual field defects and strokes'* and stated that *'this [research] changed how we look at things and how we assess'*

The benefit of the vision assessment in raising awareness of visual impairment was noted.

Dr            I'm sure the benefits of it [the vision service] has been about raising awareness and then accessibility. I'm sure that's the key to it and just having that presence on the ward.

The therapists talked about how a vision assessment supported specific aspects of their role

OT            ...for me as an occupational therapist, looking at someone's.... other deficits, mainly perception really, how big an impact really the vision will have on conducting any of the perceptual or cognitive assessments...and so, if someone is having difficulty seeing their whole environment, they've got no chance of perceiving it.

PT            And I think, you know, it's hard sometimes, like you know, when you're meeting the families and the patients, and often you have to tell people quite hard.... difficult things, like they might not walk um and, you know, yes you've had X amount of therapy but we think you're at the stage

where you're not going to get any better in hospital. And the more sort of concrete evidence you've got to support that decision, the better the patients will take it ...it's not just an opinion then, it's you know, it's supported and they're more likely to hopefully accept it.

### *Impact on Rehabilitation Process*

There was evidence that the participants thought that a vision assessment assisted patients in making decisions about their functional ability, the Physiotherapist commented *'if it [vision assessment] makes one or two people think well actually yeah I'm probably not safe to just go and drive'*. It appeared that the information from the visual assessment was being used to inform clinical reasoning when deciding whether additional therapy would be beneficial.

PT        And we need to know it [vision assessment information] as therapists because if he is gonna improve, then great, we might keep him in a bit longer, give him a longer window of therapy, whereas if you know that that's.... that's his vision pretty much, then it sort of changes our perspective a little bit.

There was also evidence that the Physiotherapist felt that the vision assessment information improved the quality of the therapy that was being offered.

PT        I suppose, I mean, they [the patients] wouldn't know, but they're getting better therapy from us as physios and occupational therapists because we're more aware of specific visual deficits...

Orth      So, you think that there is a benefit to the patient?

PT        They might not know about it, yeah.

### *The Vision Assessment Service*

The participants appeared to agree that it was important that the vision service was provided by an eye specialist with recognised skills in assessing and treating patients. And that this service should be easily accessible.

Dr            I think the minimum [vision] service would be at least somebody there, a specialist with an interest in stroke or neuro deficit, on the other end of the phone and maybe even for a written referral, to go to [for] further assessment

The participants reported that practice on the unit had changed as a result of the research and the additional vision assessment service. There was evidence that staff had begun to consider the general impact of visual impairment and were trying to ensure that the environment was adapted to suit the patient's visual status.

OT            Yeah. Even though I wasn't really aware. Now on reflection, I feel like I probably have changed um, you know, in the kitchen assessments, making sure that things are clear to them, you know, to find things.

Whilst another participant states:

PT            My gut feeling is that there won't be much difference between the two groups because I think just us knowing that they [the patient] had a visual deficit, regardless of what that visual deficit was, I think we changed our practice.

This change in practice highlighted a potential source of contamination between the two groups in the pilot RCT.



When talking about the termination of the full baseline vision assessment. There was evidence of a sense of loss for the routine vision service. The participants indicated that the vision service was a valuable asset to an organised stroke service.

Dr               ... I think by having the study, it's like giving us a taste of...what [we] could have as an addition to the...the service we already provide.

When considering their feelings about the end of the routine vision assessment service the same participant continued:

Dr               That'd be...that would be terrible now. You know, it would just seem, to me, counter intuitive to what we're trying to do with our stroke service.

There was evidence that the participants would try to use what they had gained, once the vision assessment service had been discontinued.

OT              ...I think now that the research is coming to an end, and obviously the vision assessments have come to an end, I think we will continue to muddle through and try.... and do our best to, you know, not necessarily solve the problem but compensate probably for the deficits, um you know.

## **Discussion**

Visual impairment has been shown to impact on activities of daily living and quality of life (Jones and Shinton, 2006; Gall et al, 2009; Jongbloed, 1986; Dombovy et al, 1986; Wolter et al, 2006). Uncorrected visual impairment causes difficulties with performing activities of daily living and mobility tasks (Jones and Shinton, 2006) as does visual field loss (Jongbloed, 1986; Dombovy et al, 1986, Warren, 2009) and

impaired vision is shown clearly to be a risk factor for falls in addition to being linked with depression and reduced activity of daily living performance (Ramrattan et al, 2001; Johansen et al, 2003; Corriveau et al, 2004; Marx et al, 1992).

In this pilot RCT, we hypothesised that provision of detailed information about the visual status of the patient would enhance functional recovery by altering the choice and conduct of rehabilitation. Quantitative comparative analysis of the control and experimental groups showed no significant difference in the primary outcome measure (FIM). Changes in therapy treatment were noted by therapists in only four cases. There was insufficient detail in the questionnaire responses to identify the meaning of these changes or to draw any conclusions. This data collection method proved to be ineffective within this busy stroke service. For future studies, it is likely that a small number of therapist interviews would provide greater understanding of clinical reasoning.

Our intention was to recruit 70 patients to this trial – we achieved a recruitment rate of 64 patients out of 74 patients identified as suitable for the trial. Twenty-five participants were lost to analysis with initial loss relating to death or inability to complete assessment at the initial baseline assessment. Loss from analysis through to the follow-up assessment related to death, failure to attend appointment or the increasing discharge rate from the stroke unit which led to some missing 6 week follow-up data. The latter posed a limitation to this trial as the introduction of early supported discharge to the stroke unit coincided with the early months of patient recruitment to this trial. There was no significant difference in the timing of early discharges in each group. Thus we cannot infer that patients in the experimental group were discharged earlier than those in the control group due to better targeted treatment. The outcomes measures limited the findings in this study. Many

participants were not able to complete a timed walk, alternative measures should be utilized in future studies in an in-patient stroke unit setting. It would be expected that patients undertaking therapy would improve over time and in this study the FIM was sensitive enough to measure the improvement in function for both groups. It is possible that a more sensitive measure may have picked up differences in function between the groups, although the participants in the focus group did anticipate that there would be no difference in functional outcome between the groups before the quantitative data had been analyzed, providing some additional, albeit, qualitative support for this finding.

The qualitative study indicated an inherent bias had been introduced to this trial, due to the inability to blind, care-givers and assessors to group allocation. The health care team perceived that the presence of a full baseline vision assessment enhanced their awareness of the effect of visual deficits following stroke. This was regardless of whether or not the full visual assessment details were available. There was evidence that therapists altered their intervention and adapted the treatment environment to accommodate for visual deficits in both groups. All patients entered into this trial had a visual impairment confirmed by orthoptic assessment prior to randomisation of the patient to the two groups of this trial. The therapy staff were therefore aware that patients recruited to the trial had a visual impairment. It is proposed that the precise details of the nature of visual impairment were not necessary at the time of instigating rehabilitation – the mere knowledge of presence of visual impairment was sufficient to adapt rehabilitation. This may have impacted on the validity of the randomized controlled trial results.

An Orthoptist was a participant in the focus group. The Orthoptist was not the research Orthoptist providing the vision assessment service, but was a specialist Orthoptist who worked in the hospital Ophthalmology Department . When the interactions were analysed there was evidence of a close working relationship between the Physiotherapist, the Occupational Therapist and the Physician, so whilst it is possible that the discussions in the focus group may have been influenced by the presence of the Orthoptist, the interactions indicated that the group members would have felt able to express their views in the presence of their colleagues.

The vision service was valued by the health professionals. The qualitative study provided some valuable insights and indicated that the health professionals believed that the vision assessment service increased the quality of the overall stroke service. There was a perception that the presence of the vision service had changed practice and that the termination of this service would lead to a reduction in quality of the stroke service. This perceived value supports the current UK guidelines which recommend visual assessment by specialists for any patient with a suspected visual impairment (Department of Health, 2007; Intercollegiate Stroke Working Group, 2008; Scottish Intercollegiate Guidelines Network, 2010). However, given the discrepancy between the quantitative results and the views expressed by the health professionals in the focus group, further research is required to clarify the potential benefit of a given visual assessment on functional outcomes.

Patients were not invited to participate in the focus group in this study. It was not possible to overcome this limitation in the timescale available. Future studies should endeavour to capture patients' opinions of vision services.

A strength of this study was the mixed methodology. Whilst the randomized controlled trial indicated no differences between the two groups, the qualitative study provided information about the perceived impact of the vision assessment service on outcomes and some of the possible reasons for the quantitative findings. There was evidence of a potential source of bias through contamination. Removal of bias in studies involving therapeutic interventions is recognized to be challenging (Sim and Wright, 2000; Stephenson and Imrie, 1998). Future studies need to address this issue; cluster randomization may be one means of avoiding the contamination that occurred. In this relatively novel research area; a mixed methodology is strongly recommended, as it enables an investigation of efficacy and a thorough consideration of issues arising from a study.

## **Conclusion**

The pilot RCT has shown that patients who have a visual impairment show significant functional improvement in the first 6 weeks of rehabilitation, but found no quantitative difference in functional outcome of the control or experimental groups. The detailed visual information in itself did not change functional outcome in this study. Qualitative analysis provided data which helped understand the non-significant quantitative findings. Views obtained from the health professionals indicated the perceived importance of a vision service to quality of care for stroke patients. The vision assessment was valued by members of the health care team. This study provides some useful insights into the challenges that face researchers working in this area. We have suggested some ways these challenges may be controlled or avoided. This study has highlighted the importance of qualitative phases in such trials. The provision of vision services within stroke units warrants

further investigation to determine impact to functional outcome and with vision service provision.

## **Key Points**

- Provision of visual assessment information to health professionals did not influence quantitative functional outcome in this study.
- Qualitative findings indicated perceived benefits from the provision of the vision assessment service.
- The vision assessment service within a stroke unit was valued by members of the health care team.
- A mixed methodology was a useful research design and should be utilised in future studies.

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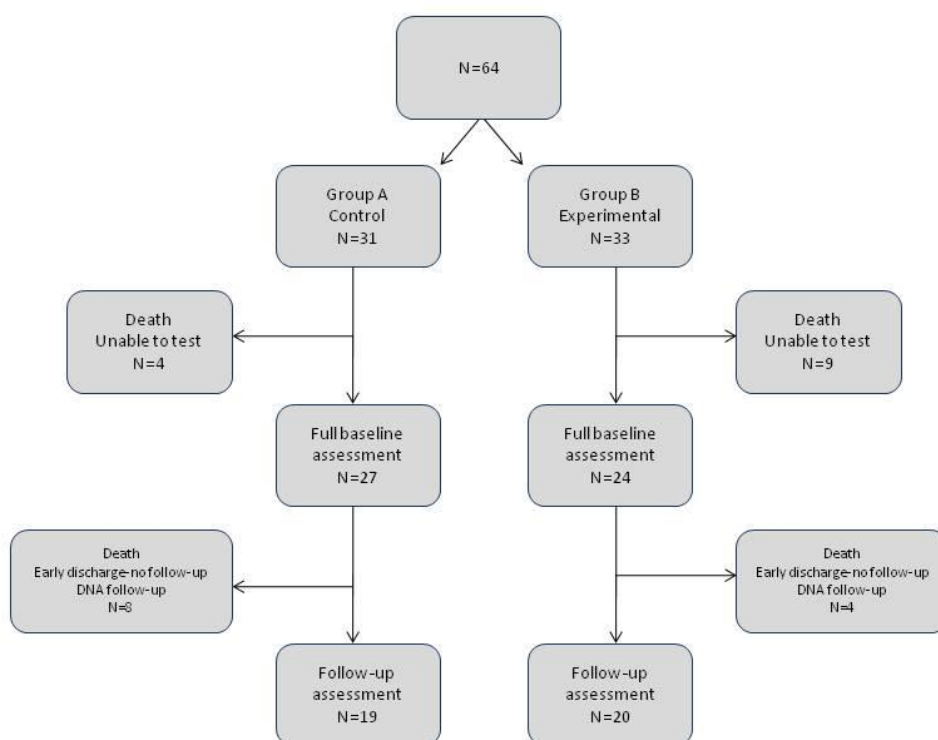
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## Tables and Figures

		Group A: Control	Group B: Experimental
<b>Number allocated</b>		31	33
<b>Gender</b>	Male	19	21
	Female	12	12
<b>Mean age at stroke onset</b>		69.35 years (SD 14.46)	70.38 years (SD 10.77)
<b>Stroke type</b>	Ischaemic	28	28
	Haemorrhage	3	4
	Combined	0	1
<b>Stroke area</b>	Cortical	12	17
	Subcortical	6	5
	Mixed	13	11
<b>Stroke laterality</b>	Right sided	22	19
	Left sided	7	12
	Bilateral	2	2
<b>Handedness</b>	Right handed	25	29
	Left handed	3	1
	Not specified	3	3
<b>Ocular diagnosis</b> <b>(Note: patients may have had an isolated visual impairment or combined visual deficits)</b>	Low vision	18	12
	Visual field loss	19	19
	Eye movement deficit	17	24
	Perceptual impairment	11	13

**Table 1**      **Features of group allocation for all recruited patients**



**Figure 1** Flow chart of group follow-up

		Group A: Control	Group B: Experimental
Number allocated		19	20
Gender	Male	11	12
	Female	8	8
Age at stroke onset		70 years (SD 11.78)	70.2 years (SD 11.27)
Stroke type	Ischaemia	16	18
	Haemorrhage	3	1
	Combined		1
Stroke area	Cortical	6	8
	Subcortical	3	5
	Mixed	9	7
Stroke laterality	Right sided	14	11
	Left sided	3	7
	Bilateral	2	2
Handedness	Right handed	15	19
	Left handed	3	1
	Not specified	1	0
Ocular diagnosis (Note: patients may have had an isolated visual impairment or combined visual deficits)	Low vision	11	7
	Visual field loss	13	14
	Eye movement deficit	11	14
	Perceptual impairment	7	9

**Table 2**      **Features of group allocation for recruited patients with full baseline and follow-up data**

	Group A: Control	Group B: Experimental
Baseline Median FIM score	73	75
6-week Follow-up Median FIM score	104	95

**Table 3**      **FIM for group allocation**